Exhibit 19-2

State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS

Exhibit to the November 25, 2009 Declaration of Philip D. Robben in Support of Defendants' Joint Motion for Partial Summary Judgment

In addition to volume purchasing, some major pharmaceutical purchasers told us that they may enter into drug bundling agreements with manufacturers to achieve greater discounts. According to one of the major pharmaceutical purchasers we surveyed, in a bundling agreement, a manufacturer agrees to provide a discount on one prescription drug, usually a single-source drug, only if the major pharmaceutical purchaser also agrees to purchase or include on its formulary other drugs produced by the manufacturer. One of the hospital buying groups we surveyed purchases non-drug items such as medical, surgical, laboratory, dietary, and radiology supplies and may bundle all of these items plus drugs into one discount purchase agreement. However, some major pharmaceutical purchasers told us they avoid entering bundling agreements because they believe bundling limits their ability to negotiate the best possible price for each drug.

Finally, one major pharmaceutical purchaser we surveyed mentioned other factors it believes are key to successfully negotiating price discounts with prescription drug manufacturers. These include the ability of the purchaser to make a long-term commitment to the manufacturer to convince the manufacturer that it is a credible business partner and will pay all its bills on schedule, and to assure the manufacturer that it will not buy prescription drugs at the discounted price and then resell them to other hospitals or other countries for a profit. Another factor is a good working relationship between the purchaser and the manufacturer.

According to the major pharmaceutical purchasers we surveyed, negotiated discount contracts may take different forms. Contracts may be single year or multiple year. Some contracts guarantee a fixed price for the life of the contract. In addition, multiple-year contracts may contain provisions that allow either party to renegotiate the contract terms during the life of the contract in response to changing circumstances. Contracts may offer per unit discounts that increase in size with increasing volumes of prescription drugs purchased.

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A major pharmaceutical purchaser may receive the reduced price in a variety of ways. If a purchaser operates its own pharmacies, it may simply purchase the prescription drugs directly from the manufacturer at the reduced price. However, some manufacturers only sell through wholesalers. In some cases, a wholesaler may agree to sell the prescription drugs to the purchaser at the discounted price negotiated between the manufacturer and the purchaser. The wholesaler later bills the manufacturer for the discount provided to the purchaser. One of the purchasers we surveyed told us it facilitates this type of payment arrangement by entering into prime vendor agreements, dealing exclusively with one or two wholesalers. Alternatively, the purchaser may buy the prescription drugs from the wholesaler at the wholesaler's regular price and then receive a rebate from the drug manufacturer for the difference between the price the purchaser paid to the wholesaler and the negotiated price.

How Some Major Purchasers Apply Cost Controls

The participants in our survey of major pharmaceutical purchasers use a variety of methods to manage the overall cost of the drug benefits they provide to patients. However, some of the major pharmaceutical purchasers we surveyed are more active than others in applying utilization and price controls to manage their drug benefits. A more active purchaser may employ more utilization and price controls in managing the use of drugs in its facilities. The more active the purchasers are in managing their drug benefits, the more opportunities become available to control drug expenditures.

The major pharmaceutical purchasers we surveyed that merely acquired drugs for their organizations but did not dispense drugs, such as the three governmental organizations or the two buying groups, typically focused their efforts in lowering drug costs by attempting to lower the price of the drugs they were purchasing. Table 1 shows the strategies that the government organizations and hospital buying groups we surveyed may use to control their drug expenditures.

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Table 1 Utilization and Price Controls Used by Government Organizations and Hospital Buying Groups

Utilization and Price Controls	Department of Veterans Affairs	Department of General Services	Los Angeles County	Hospital Buying Group A	Hospital Buying Group B
Manufacturers' price discount	Yes	Yes	Yes	Yes	Yes
Product bundling	No	No	Yes	Yes	Yes
Drug formulary	NA	NA	NA	NA	NA
Prior authorization	NA	NA	NA	NA	NA
Generic substitution	No	No	No	Yes	Yes
Therapeutic substitution	No	No	No	No	No
Prescriber education	NA	NA	NA	Yes	No
Prescriber financial incentives	NA	NA	NA	No	No
Electronic data base	NA	NA	NA	NA	NA
Drug utilization review	NA	NA	NA	NA	NA
Contract pharmacy	NA	NA	NA	NA	NA
Reimbursement limits	NA	NA	NA	NA	NA
Patient copayments	NA	NA	NA	NA	NA

Source: Surveys conducted by the Office of the Auditor General.

Note: NA refers to utilization and price controls that may not have been used by government organizations or hospital buying groups because these entities did not dispense drugs.

These purchasers focused on the price of drugs they purchased by competitively bidding the price of individual drug items. Three purchasers stated that they negotiate price discounts by entering "bundling" agreements, agreeing to purchase multiple-source drugs from a particular vendor in exchange for a price discount on that vendor's single-source drug. (Vendors consist of manufacturers and wholesalers.) One of the three purchasers stated it sometimes entered purchasing agreements with drug vendors who offered rebates that returned a percentage of the

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purchase price to the purchaser or offered lower unit prices. Price rebates were sometimes tied to the volume of the drug purchased. Volume-based pricing allowed the purchaser to pay a lower unit price as its purchases increased.

The hospitals and health maintenance organizations (HMOs) we surveyed employed both utilization and price controls to control the use of drugs in their facilities and to manage the overall cost of their drug benefits. Table 2 shows the strategies that the hospitals and HMOs we surveyed use to control their drug expenditures. One of the five HMOs we surveyed delivers its services through two different membership plans. This HMO is identified in Table 2 as A1 and A2.

Table 2 Utilization and Price Controls Used by Hospital and Health Maintenance Organizations (HMOs)

Utilization and Price Controls	Hospital A	Hospital B	HMO A1	HMO A2	HMO B	HMO C	HMO D	HMO E
Manufacturer price discount	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Product bundling	No	Yes	Yes	Yes	No	No	No	No
Drug formulary	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Prior authorization	Yes	Yes	Yes	Yes	Yes	No	No	NA
Generic substitution	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Therapeutic substitution	No	Yes	Yes	No	No	No	Yes	No
Prescriber education	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Prescriber financial incentives	No	No	No	No	Yes	Yes	Yes	No
Electronic data base	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Drug utilization review	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Contract pharmacy	No	No	No	Yes	Yes	Yes	No	No
Reimbursement limits	NA	NA	NA	Yes	Yes	Yes	NA	Yes
Patient copayments	No	No	Yes	Yes	Yes	Yes	Yes	Yes

Source: Surveys conducted by the Office of the Auditor General.

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Hospitals employ both utilization and pricing strategies to control the use of drugs in their facilities and to contain the growth of their drug expenditures. Both of the hospitals we surveyed stated they manage a restricted formulary that lists the drugs approved for use in the hospital. Both hospitals require physicians to submit authorization requests before the hospital pharmacy will dispense a prescription for a non-formulary drug. Also, both of the hospitals require the hospital pharmacy to substitute generic drugs for brand name items unless the physician instructs otherwise. One of the two hospitals allows pharmacists to substitute therapeutically equivalent drugs. Both hospitals conduct some form of physician education to advise physicians of the therapeutic value of drugs. Both hospitals monitor drug utilization with an on-line data system.

The HMOs we surveyed also employ utilization and pricing strategies to control the use of drugs by plan members and to contain the growth of their drug expenditures. Three of the HMOs we surveyed did not operate their own pharmacies. Two of the three HMOs had entered into agreements with selected pharmacies throughout the State where the beneficiaries of these HMOs could get their prescriptions filled. The two HMOs that used these contract pharmacies controlled drug utilization by limiting the amount they reimbursed contract pharmacies for dispensing drugs. Such agreements were one way HMOs encouraged pharmacies to dispense the lowest priced drug when medically appropriate. The two HMOs that used contract pharmacies to dispense drugs to patients had implemented maximum allowable prices for some generic drugs. Maximum allowable prices encourage pharmacies to take the cost of the drug into account when dispensing.

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Chapter 2 Attempts To Control the Growth in Medi-Cal Drug Expenditures

Chapter Summary

The California Medical Assistance Program (Medi-Cal) uses both utilization and price strategies in its attempt to stem the increase in its drug expenditures. The establishment of a restrictive formulary, the requirement for prior authorization when non-formulary drugs are prescribed, the requirement that generic drugs be dispensed whenever possible, and the imposition of dispensing, prescribing, and payment restrictions are all examples of utilization controls instituted by Medi-Cal. However, as its primary way of controlling the price of pharmaceuticals, Medi-Cal uses maximum limits on the amount it reimburses pharmacies serving Medi-Cal patients. Also, recently, the Department of Health Services (department) implemented a drug discount program designed to reduce the prices Medi-Cal pays for drugs. Through this program, the department negotiates directly with drug manufacturers for rebates on pharmaceuticals. The department estimates the drug discount program will save Medi-Cal $3.3 million ($1.65 million in General Fund moneys and $1.65 million in federal moneys) in fiscal year 1990-91. However, this estimate does not take into account $659,000 in budgeted costs associated with the operation of the drug discount program.

Background

Under Medi-Cal, beneficiaries may receive prescription drugs that are included on a list established by the department. This list is known as the Medi-Cal list of contract drugs and includes drugs from most therapeutic categories. Therapeutic categories are classifications of drugs that address specific medical problems. For example, the list of contract drugs includes such therapeutic categories as antibiotics and cardiac and gastrointestinal drugs. Once drugs on the list are prescribed by licensed practitioners,

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Medi-Cal beneficiaries obtain them through providers, usually pharmacists. When a provider supplies a prescribed drug to a beneficiary, the provider also submits a claim for payment for services to a non-governmental fiscal intermediary who processes Medi-Cal claims for reimbursement on behalf of the State. The fiscal intermediary, using established criteria, determines whether a provider's claim should be paid.

Restrictive Formulary

The department has made numerous attempts to stem the growth of Medi-Cal drug expenditures. For example, the department has attempted to control drug expenditures through the use of a list of drugs that it prefers be prescribed to Medi-Cal beneficiaries. Established under Title 22 of the California Code of Regulations, this list was known as the formulary. Legislation adopted in 1990 changed the name of the Medi-Cal formulary to the list of contract drugs. Medi-Cal's formulary contained more than 500 drugs and identified drugs that could be provided to Medi-Cal beneficiaries without receiving prior authorization from the department. The availability of many drugs listed on the formulary was also limited by restricting such items as the quantity, strength, and dosage forms and the medical condition to be treated through a given drug. Any additions of drugs to the formulary were done through the adoption of state regulation. On July 1, 1990, Medi-Cal's drug formulary became known as the list of contract drugs. With the establishment of the drug discount program on July 31, 1990, the addition of a drug to the list of contract drugs no longer requires the adoption of a state regulation.

Prior Authorization

The department requires that providers seek prior authorization for certain drugs before these drugs are dispensed to Medi-Cal beneficiaries. When a doctor prescribes a drug for a Medi-Cal beneficiary that is not on the list of contract drugs, the provider, generally a pharmacist, must receive authorization to seek reimbursement for the cost of the drug. The patient's physician or pharmacist may request authorization from a regionally based Medi-Cal consultant, who is a licensed pharmacist, through a treatment authorization request. Authorization may only be granted for drugs that are medically necessary and are the lowest priced to meet the beneficiary's medical needs.

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Required Generic Substitution

Medi-Cal also uses generic substitution to control drug costs. Generic substitution reduces the cost per prescription for drugs available from multiple suppliers. According to Title 22 of the California Code of Regulations, pharmacists are required to substitute the lowest priced generic drug for the drug that was prescribed, provided the pharmacists have the less expensive generic drug in stock and the drug meets the medical needs of the beneficiary.

Copayment

With certain exceptions, Medi-Cal recipients are obligated to copay $1.00 for each drug prescription or refill. However, the collection of a copayment by pharmacists is optional and may be either collected and retained or waived. However, a pharmacist cannot deny services to an individual solely because of that person's inability to copay. Any copayment collected by a pharmacist is retained by the pharmacist and is in addition to any reimbursement due for services rendered under Medi-Cal. According to the department, there is no requirement for pharmacies to report on copayment collections. Consequently, there is no information available to determine the extent to which copayments are collected.

Dispensing, Prescribing, and Payment Restrictions

To limit Medi-Cal drug expenditures, the department has also placed restrictions on how prescription drugs are dispensed, prescribed, and paid for under Medi-Cal. Medi-Cal limits the quantity of each prescription, the number of prescriptions that can be filled within a certain period, and the specific use of drugs included on the list of contract drugs. According to Title 22 of the California Code of Regulations, Medi-Cal beneficiaries cannot receive more than a 100-day supply of a prescription drug from a provider, except under certain circumstances. In addition, the list of contract drugs identifies drugs that must be dispensed in minimum quantities of 100 tablets or capsules. This restriction generally applies to drugs that require long-term use. As a way of

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enforcing the restriction, Medi-Cal will fully pay the provider only when a minimum quantity of at least 100 tablets or capsules is furnished to the beneficiary.

In addition, many drugs on the list of contract drugs are subject to other restrictions. Although Medi-Cal does not directly limit the number of prescriptions that can be given to Medi-Cal beneficiaries, it does restrict the amount of payment per drug that it makes during a specified period. After pharmacists fill prescriptions for drugs on the list of contract drugs, they receive payment from Medi-Cal for both the service of dispensing the drug to the patient and the cost of the ingredients in the drug. To prevent pharmacists from overdispensing certain drugs, Medi-Cal will not pay the dispensing fee when the same drug is provided to the same beneficiary more than three times in a 75-day period.

Finally, Medi-Cal restricts the use of some drugs on the list of contract drugs to specific medical problems. For example, the drug nalidixic acid is restricted for use to urinary and prostatic infections; Medi-Cal will not pay for this drug if it is provided to treat other medical problems unless prior authorization has been received. Pharmacists must keep records that meet state regulations for dispensed drugs subject to these specific-use restrictions.

Drug Utilization Review

In the Medi-Cal program, Chapter 1340 of the Statutes of 1987 established a pilot drug utilization review, which the department is responsible for administering. To operate the drug utilization review, the department has contracted with the Virginia Computer Company, which, in turn, entered into a contract with the Stanford Research Institute to evaluate the pilot program.

The drug utilization review committee assesses whether a physician should have prescribed (or a pharmacy should have dispensed) a particular medication given the medication's suggested uses, its interactions with other drugs the patient is using, and the patient's diagnosis. If the committee finds that physicians or pharmacists may have prescribed or dispensed

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medications inappropriately, the committee notifies the physicians or pharmacists of its concern. Through this type of intervention, the program is intended to improve the therapeutic outcome for Medi-Cal beneficiaries.

In accordance with Chapter 1340 of the Statutes of 1987, our office was also responsible for assessing the cost-effectiveness of the pilot drug utilization review. To do this review, we contracted with the consulting company of Ernst and Young. In its May 1991 report, Ernst and Young concluded that the program resulted in the decreased use of drugs, outpatient services, and hospital care for a small group of Medi-Cal recipients during the review period. However, the cost savings associated with the reductions in services were too small to prove the cost-effectiveness of the program.

Reimbursement Limits

A reimbursement limit is a ceiling on what Medi-Cal will reimburse a pharmacist for a particular drug the pharmacist has provided to a Medi-Cal beneficiary. Federal regulations require states to base reimbursement for drugs on the best estimate of the price generally and currently paid by providers for a drug sold by a particular manufacturer or labeler. As a result, to limit drug costs, Medi-Cal has established several reimbursement limits, depending on the drug dispensed and the drug's manufacturer, for pharmacies dispensing prescriptions to Medi-Cal beneficiaries. In general, pharmacies are reimbursed for a drug's ingredient cost plus a dispensing fee. According to a department official, a dispensing fee was established to provide participating pharmacists with a reasonable reimbursement to cover their overhead and profit.

California regulation states that generally the cost for dispensed drugs should equate to the lowest of four reimbursement limits: the pharmacies usual and customary charges to the general public; the Estimated Acquisition Cost (EAC) plus a dispensing fee; the Maximum Allowable Ingredient Cost (MAIC) plus a dispensing fee; or the Federal Allowable Cost (FAC) plus a dispensing fee. With certain exceptions, Medi-Cal reimburses pharmacies a standard dispensing fee of $4.05 for each prescription filled.

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Estimated Acquisition Cost

For all drugs manufactured or distributed by a group of 11 designated pharmaceutical companies, which are identified in regulation, the EAC is the direct price. A pharmacy pays the direct price to one of the 11 manufacturers when purchasing a drug directly from the manufacturer. Medi-Cal's EAC reimbursement limit for the products of these specific manufacturers is the direct price because providers generally buy directly from these manufacturers. In contrast, for all other drugs, the EAC is the average wholesale price (AWP) minus 5 percent. (See page 14 for a definition of average wholesale price.) Medi-Cal's EAC reimbursement limit of the AWP minus 5 percent is applicable to all other products because providers generally purchase these products through wholesalers. By making a distinction between purchases from manufacturers and those from wholesalers, Medi-Cal is able to more accurately capture the price generally and currently paid by providers.

Change in EAC Regulation

Before October 16, 1989, the EAC was defined in California regulation as the AWP or other price the department determines to be the price generally and currently paid by providers for a drug marketed or sold in a standard package. However, the practice of reimbursing pharmacies at an undiscounted AWP was questioned by both the inspector general of the federal Department of Health and Human Services and the federal Health Care Financing Administration (HCFA). In a 1989 report, the inspector general cited a report issued in 1984 entitled Changes to the Medicaid Prescription Drug Program Could Save Millions. The 1984 report concluded that, on average, pharmacies buy drugs for 15.9 percent below the AWP. In August 1989, the HCFA provided clarification regarding the use of the published AWP as a State's determination of the EAC. The HCFA pointed out that the EAC means a state's best estimate of the price generally and currently paid by providers. Further, the HCFA pointed out the preponderance of evidence demonstrating that the AWP overstates the prices that pharmacies actually pay for drugs by as much as 10 to 20 percent because the AWP does not reflect discounts, premiums, special offers, or other incentives that manufacturers or wholesalers provide to pharmacists.

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Consequently, the HCFA stated that, without valid documentation to the contrary, a published AWP level as a state determination of the EAC without a significant discount being applied would not be an acceptable estimate of prices generally and currently paid by providers.

Moreover, in October 1989, the inspector general issued a report entitled Uses of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program. In this report, the inspector general found that, on average, pharmacies were buying drugs for 15.5 percent below the AWP and concluded that the AWP was not a meaningful payment level and that it should not be used for making reimbursements. The inspector general recommended that the HCFA continue to require state Medicaid agencies, such as Medi-Cal, to discount the AWP when making program reimbursements.

As a result of the HCFA's August 1989 clarification that state Medicaid agencies discount the AWP when making program reimbursements, the department amended the method of reimbursement. In September 1989, an emergency regulation was filed amending California regulations and modifying the definition of the EAC as it relates to Medi-Cal payments to providers of drugs. Consequently, beginning on October 16, 1989, pharmacists providing drugs under the Medi-Cal program where the EAC is the reimbursement limit used and where a direct price does not apply began receiving cost reimbursements at the AWP minus 5 percent instead of at the pre-amendment limit. According to the department, the AWP minus 5 percent was established because it is the State's best estimate of the price generally and currently paid by providers for certain drugs.

Maximum Allowable Ingredient Cost

The MAIC, independently established by the department, is a maximum cost reimbursement limit, or price for certain multiple-source drugs on the Medi-Cal list of contract drugs. According to the department, MAICs are generally established for highly used multiple-source drugs where the difference between

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the generic and brand name price is significant. Each MAIC reimbursement limit is established by the department and based on the price of a reference product that the department determines to be generically equivalent in quality to products used by physicians throughout the State. The reference product must be generally available to pharmacies, through customary distribution channels, in sufficient quantities to meet the needs of Medi-Cal.

For example, the department stated that when it established a MAIC for the generic drug allopurinol, it first surveyed the numerous manufacturers that produce allopurinol to obtain therapeutic equivalency data and to determine if their product is available throughout the State. At the same time, the department also obtained each manufacturer's current AWP price for the drug. The MAIC price was then established by selecting from those manufacturers that responded to the survey the lowest or one of the lowest priced therapeutic drugs that met the therapeutic equivalency and availability criteria. MAICs are updated monthly to reflect current marketplace price changes.

Federal Allowable Cost

A FAC, established independently by the federal Department of Health and Human Services (HHS), is an upper limit of payment for certain multiple-source drugs. In effect, the federally required FAC is administered by Medi-Cal in the same manner as the MAICs. The purpose of the FAC upper limits is to take advantage of savings resulting from the availability of less costly, but safe and effective, generic drug substitutes.

The major difference between the FACs and the MAICs is that the HHS periodically issues changes in the FAC list of drugs and respective price limits whereas the MAIC price limits are established and updated monthly by the department. Also, the formula that the HCFA uses in calculating the FACs is different from the process California uses in determining the MAICs, and a difference can exist between the FAC and MAIC prices for the same drug. Generally, the FAC limits are the lower of the two.

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When a drug is listed on both the FAC and MAIC price lists, the maximum reimbursement allowed is the lower of the FAC or MAIC.

When medically necessary, approval of payment may be obtained for a product whose price exceeds the FAC or MAIC price limits by requesting prior authorization from a Medi-Cal consultant. For example, the FAC reimbursement limit for 100 tablets of 2 mg strength generic albuterol is $9.66. However, if medically necessary, Medi-Cal would approve payment for Ventolin, a generically equivalent brand name drug, whose current price is $29.75.

Variation in Amounts Pharmacies Bill and Are Reimbursed

A reimbursement limit is a ceiling on what Medi-Cal will reimburse a pharmacist for a particular drug the pharmacist has provided to a Medi-Cal beneficiary. However, the amount the pharmacist bills Medi-Cal for filling that prescription may not always coincide with the Medi-Cal reimbursement limit. For example, some pharmacists, who may not know all the reimbursement limits, may simply bill Medi-Cal for the same amount they would charge their other customers. However, reimbursements for drugs covered under Medi-Cal will only be made at the Medi-Cal reimbursement limit.

We surveyed six pharmacists to obtain the amount their pharmacy would charge Medi-Cal for a sample of six multiple-source prescription drugs. (The survey included one pharmacist at a chain pharmacy and one at a pharmacy specializing in providing drugs to skilled nursing facilities.) We then compared the amounts that these pharmacies would charge to Medi-Cal with the amounts for Medi-Cal reimbursement limits to determine whether a significant difference existed between the amount that the pharmacies would have billed and the amount that Medi-Cal would have reimbursed. Table 3 shows the variation in pharmacy charges to Medi-Cal, by drug and manufacturer, for each of the six pharmacies in our sample. In addition, the table reflects the difference in Medi-Cal reimbursement limits.

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Table 3

Variations In Medi-Cal Reimbursement Limits

Generic Drug Name Strength Quantity	Pharmacy	Manufacturer	Amount Pharmacy Would Have Charged Medi-Cal[a]	Estimated Acquisition Cost: Direct Price	Estimated Acquisition Cost: Average Wholesale Price Minus 5 Percent[b]	Maximum Allowable Ingredient Cost[b]	Federal Allowable Cost[b]
Amitriptyline	Pharmacy A	Goldline	$ 7.35		$ 7.04	$12.61	
Hydrochloride	Pharmacy B	Purepac	$ 8.03		$12.51	$12.61	
50mg	Pharmacy C	Purepac	$12.91		$12.51	$12.61	
100 tablets	Pharmacy D[c]	Rugby	$12.61		$ 8.12	$12.61	
	Pharmacy E[d]	Barr	$ 7.36		$ 6.96	$12.61	
	Pharmacy F	Geneva	$ 7.20		$ 9.18	$12.61	
Chloral Hydrate	Pharmacy A	Goldline	$11.70		$11.18	$ 9.14	
500mg	Pharmacy B	Goldline	$ 9.14		$11.18	$ 9.14	
100 tablets	Pharmacy C	Goldline	$ 9.44		$11.18	$ 9.14	
	Pharmacy D[c]	Squibb	$ 9.14	$13.85		$ 9.14	
	Pharmacy E[d]	Goldline	$11.90		$11.18	$ 9.14	
	Pharmacy F	H.L. Moore	$ 9.15		$10.20	$ 9.14	
Acetaminophen	Pharmacy A	Rugby	$ 8.82		$ 8.25	$ 7.43	$ 8.14
with Codeine	Pharmacy B	Parmed	$ 8.14		$ 7.70	$ 7.43	$ 8.14
30mg/300-325mg	Pharmacy C	Parmed	$ 8.44		$ 7.70	$ 7.43	$ 8.14
45 tablets/capsules	Pharmacy D[c]	Purepac	$ 8.15		$ 7.43	$ 7.43	$ 8.14
	Pharmacy E[d]	Lanman	$ 8.13		$ 7.23	$ 7.43	$ 8.14
	Pharmacy F	Purepac	$ 8.14		$ 7.43	$ 7.43	$ 8.14
Meclizine Hydrochloride	Pharmacy A	Rugby	$ 8.40		$ 8.04	$ 7.27	$ 8.15
25mg	Pharmacy B	Goldline	$ 8.15		$ 7.76	$ 7.27	$ 8.15
100 tablets	Pharmacy C	Sidmark	$ 8.45		$ 8.41	$ 7.27	$ 8.15
	Pharmacy D[c]	Rugby	$ 5.24		$ 8.04	$ 7.27	$ 8.15
	Pharmacy E[d]	Major	$ 7.82		$ 7.96	$ 7.27	$ 8.15
	Pharmacy F	Geneva	$ 8.15		$ 7.81	$ 7.27	$ 8.15
Promethazine with	Pharmacy A	Geneva	$12.41		$11.89	$11.80	$10.96
Phenylephrine & Codeine	Pharmacy B	Geneva	$10.96		$11.89	$11.80	$10.96
480cc	Pharmacy C	Barre	$11.25		$12.03	$11.80	$10.96
	Pharmacy D[c]	Barre	$ 9.67		$12.03	$11.80	$10.96
	Pharmacy E[d]	Geneva	$14.38		$11.89	$11.80	$10.96
	Pharmacy F	Not stocked					

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Generic Drug Name Strength Quantity	Pharmacy	Manufacturer	Amount Pharmacy Would Have Charged Medi-Cal[a]	Estimated Acquisition Cost			
				Direct Price	Average Wholesale Price Minus 6 Percent[b]	Maximum Allowable Ingredient Cost[b]	Federal Allowable Cost[b]
Propranolol Hydrochloride 40mg 100 tablets	Pharmacy A	Goldline	$ 9.85		$ 9.42	$13.08	$ 5.78
	Pharmacy B	Warner-Chilcott	$ 5.70		$20.64	$13.08	$ 5.78
	Pharmacy C	Warner-Chilcott	$ 6.08		$20.64	$13.08	$ 5.78
	Pharmacy D[c]	Purepac	$ 5.78		$12.32	$13.08	$ 5.78
	Pharmacy E[d]	Roxane	$ 8.56		$11.16	$12.08	$ 5.78
	Pharmacy F	Lederle	$ 5.78	$18.60		$13.08	$ 5.78

Source: Telephone survey of selected pharmacists conducted in June 1991, and data supplied by staff at the Department of Health Services.

[a]Includes a dispensing fee
[b]Includes a dispensing fee of $4.08
[c]Chain pharmacy
[d]Pharmacy specializing in providing drugs to skilled nursing facilities

Our survey of pharmacists revealed that a significant difference exists in the amount the pharmacies would have billed Medi-Cal for the same prescription drug. Further, a significant difference exists in the amount Medi-Cal would have reimbursed six different pharmacies for the same prescription drug.

However, Medi-Cal does not always reimburse the pharmacies the amount that the pharmacies bill. Rather, Medi-Cal reimburses the pharmacy the lower of what the pharmacy normally charges its customers or the applicable reimbursement limit. In Table 4, we compare the amounts that each of the pharmacies would have been reimbursed for each of the six sample prescription drugs.

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Table 4

Variations in Medi-Cal Reimbursement Amounts to Six Pharmacies

Pharmacy	Generic Drug Name	Manufacturer	Medi-Cal Reimbursement Amount	Medi-Cal Reimbursement Limit[a]
Pharmacy A	Amitriptyline Hydrochloride	Goldline	$ 7.04	AWP-5%
	Chloral Hydrate	Goldline	9.14	MAIC
	Acetaminophen with Codeine	Rugby	6.14	FAC
	Meclizine Hydrochloride	Rugby	6.15	FAC
	Promethazine with Phenylephrine & Codeine	Geneva	10.96	FAC
	Propranolol Hydrochloride	Goldline	5.78	FAC
	Total		**$45.21**	
Pharmacy B	Amitriptyline Hydrochloride	Purepac	$ 8.03	Amount billed
	Chloral Hydrate	Goldline	9.14	MAIC/Amount billed
	Acetaminophen with Codeine	Parmed	6.14	FAC/Amount billed
	Meclizine Hydrochloride	Goldline	6.15	FAC/Amount billed
	Promethazine with Phenylephrine & Codeine	Geneva	10.95	Amount billed
	Propranolol Hydrochloride	Warner-Chilcott	5.70	Amount billed
	Total		**$46.11**	
Pharmacy C	Amitriptyline Hydrochloride	Purepac	$12.51	AWP-5%
	Chloral Hydrate	Goldline	9.14	MAIC
	Acetaminophen with Codeine	Parmed	6.14	FAC
	Meclizine Hydrochloride	Sidmark	6.15	FAC
	Promethazine with Phenylephrine & Codeine	Barre	10.96	FAC
	Propranolol Hydrochloride	Warner-Chilcott	5.78	FAC
	Total		**$50.68**	
Pharmacy D[b]	Amitriptyline Hydrochloride	Rugby	$ 8.12	AWP-5%
	Chloral Hydrate	Squibb	9.14	MAIC/Amount billed
	Acetaminophen with Codeine	Purepac	6.14	FAC
	Meclizine Hydrochloride	Rugby	5.24	Amount billed
	Promethazine with Phenylephrine & Codeine	Barre	9.87	Amount billed
	Propranolol Hydrochloride	Purepac	5.78	FAC/Amount billed
	Total		**$44.09**	
Pharmacy E[c]	Amitriptyline Hydrochloride	Barr	$ 6.96	AWP-5%
	Chloral Hydrate	Goldline	9.14	MAIC
	Acetaminophen with Codeine	Lemmon	6.14	FAC
	Meclizine Hydrochloride	Major	6.15	FAC
	Promethazine with Phenylephrine & Codeine	Geneva	10.96	FAC
	Propranolol Hydrochloride	Roxane	5.78	FAC
	Total		**$45.13**	
Pharmacy F	Amitriptyline Hydrochloride	Geneva	$ 7.20	Amount billed
	Chloral Hydrate	H.L. Moore	9.14	MAIC
	Acetaminophen with Codeine	Purepac	6.14	FAC/Amount billed
	Meclizine Hydrochloride	Geneva	6.15	FAC/Amount billed
	Promethazine with Phenylephrine & Codeine	Not stocked		
	Propranolol Hydrochloride	Lederle	5.78	FAC/Amount billed

[a]AWP-5% = Average wholesale price minus 5 percent
MAIC = Maximum allowable ingredient cost
FAC = Federal allowable cost
Amount billed = Amount that would have been billed to Medi-Cal by pharmacy
[b]Chain pharmacy
[c]Pharmacy specializing in providing drugs to skilled nursing facilities

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Table 4 shows that, when the reimbursement amounts for all six prescription drugs in our sample are combined, one pharmacy would have been reimbursed at an amount significantly less than the pharmacy that would have received the highest total reimbursement. The lowest total reimbursement of $44.09 would have been to Pharmacy D, and the highest total reimbursement of $50.68 would have been to Pharmacy C, a difference of $6.59, or 15 percent. Pharmacy D's reimbursement would have been less primarily because reimbursement for the prescription drug amitriptyline hydrochloride, at the AWP minus 5 percent, was $8.12 whereas the reimbursement to Pharmacy C for the same drug, also at the AWP minus 5 percent, would have been $12.51, a difference of $4.39. This difference occurred because pharmacies D and C obtain amitriptyline hydrochloride from different manufacturers.

The HCFA has reported that most large chains, such as Pharmacy D in our sample, have altered the traditional market channels by creating their own warehouses to replace, in many ways, the wholesaler. By doing this, a chain can buy in much larger quantities than individual pharmacies, resulting in lower prices because of volume discounts. Because Pharmacy D, a chain pharmacy, would have been reimbursed the lowest total of $44.09 when all six drugs are combined, the State would have shared in the savings that Pharmacy D was able to effect.

The Medi-Cal Drug Discount Program

In July 1990, legislation was passed establishing a new strategy designed to slow the growth of Medi-Cal drug expenditures. In accordance with Chapters 456, 457, 1643, and 1694 of the Statutes of 1990, the department adopted, on a pilot basis, the drug discount program, which is effective until January 1, 1993. The drug discount program allows the department to begin negotiating discounts on drugs paid for through Medi-Cal.

According to the department's acting chief negotiator, the primary objective of the drug discount program is to obtain significant discounts on the price of pharmaceuticals. To

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accomplish this, the department can take advantage of discount prices that manufacturers provide to other high-volume purchasers of drugs. Section 14105.33 of the Welfare and Institutions Code authorizes the department to enter into contracts with manufacturers of drugs for rebates on drugs purchased through Medi-Cal. The amount of a rebate, which is defined in Section 14105.31 of the Welfare and Institutions Code as an equalization payment amount, is based on the difference between the manufacturer's price typically charged to wholesalers and the manufacturer's best price. Best price is defined as the price negotiated between the department and the manufacturer or the lowest price the manufacturer sells the drug for to another entity that has a contract with the manufacturer.

By March 1991, the department had negotiated rebate contracts with 15 drug manufacturers, and it has estimated that these contracts will save Medi-Cal $3.3 million ($1.65 million in General Fund moneys and $1.65 million in federal moneys) during fiscal year 1990-91. However, in our June 1991 report entitled A Review of the Department of Health Services' Estimate of Savings Resulting From the Drug Discount Program (Report P-113), we indicated that the department's $3.3 million estimate did not take into consideration the budgeted $659,000 in state costs associated with operating the drug discount program.

Another objective of the drug discount program is to make a greater selection of drugs available to Medi-Cal beneficiaries. Before this program was established, drugs for which Medi-Cal would reimburse could be added only by regulation, a process that, for two drugs we researched, took approximately 15 months. Now the department may add new single-source drugs to the list of contract drugs when the department and the manufacturers negotiate rebate contracts, with certain exceptions. For two drugs we researched, the process of adding these drugs through negotiation took approximately four months for one drug and seven months for the other.

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Under the state regulation process, manufacturers or other interested parties petitioned the department to add a drug to the formulary. The department then drafted a proposed state regulation that would have the effect of adding the drug to the formulary. The department's medical therapeutics and drug advisory committee would then evaluate the drug based on the safety, efficacy, cost, need, and potential for misuse and make written recommendations to the director of the department. The committee then was required to make public its recommendations about adding the drug to the formulary. After the recommendations were made public, the director made the decision to add the drug or not. If the director determined that the drug should be added, the final regulation was sent for review to the Office of Administrative Law (office). The office ensured all legal and procedural requirements were followed in the adoption of the new regulation. Once the office approved the regulation, it generally became effective 30 days after the office filed the regulation with the secretary of State.

Under the drug discount program, it is not necessary to adopt a new state regulation to add a drug to the list of contract drugs. A manufacturer of a single-source drug will petition the department to add a drug to the list. Then, according to California law, a Medi-Cal drug advisory committee will evaluate the drug based on the safety, efficacy, cost, need, and potential for misuse. In addition, department staff also evaluate the drug based on the same criteria. However, according to the department's deputy director of medical care services, as of July 1991, a Medi-Cal drug advisory committee has not yet been appointed. At the present time, only the department staff are performing the evaluation. After the drug has been evaluated, the department schedules a time for the department and the manufacturer to negotiate a rebate contract. After negotiations are conducted, the director of the department decides whether the petitioned drugs should be added to the list of contract drugs. Once the director agrees that the drug should be added to the list, it may take from 60 to 90 days to actually add the drug to the list of contract drugs.

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According to the department's pharmaceutical program consultant, since the implementation of the drug discount program, 35 drugs have been added to the list of contract drugs, as of August 1, 1991. The drug discount program has not replaced or eliminated any of the utilization or price controls that were part of the Medi-Cal drug benefit before the implementation of the program.

Federal Cost Controls

The federal government has also taken steps to contain the prescription drug expenditures of state Medicaid programs. The federal Health Care Financing Administration (HCFA) oversees the Medicaid program, which, together with state governments, provides basic health services, including prescription drugs, to public assistance recipients, low-income individuals and families, and medically needy individuals. Through Medicaid, the federal government provides matching funds to states that have instituted medical care programs, such as Medi-Cal. Through the Omnibus Budget Reconciliation Act of 1990, enacted on November 5, 1990, the federal government implemented its own version of a drug discount program. This legislation requires drug manufacturers wanting to do business with state Medicaid programs, such as Medi-Cal, to enter into rebate agreements with the federal government, which provides a discount on the price of prescription drugs provided to program recipients. However, Section 1927(a)(i) of Title XIX of the Social Security Act, included in the Omnibus Budget Reconciliation Act of 1990, does include an exception to this provision. Namely, states may be authorized to enter directly into their own agreements with drug manufacturers if the state agreements meet certain federal criteria.

In November 1990, the department formally requested that the HCFA waive the requirement that the department participate in the federal program. The department requested this waiver so that it could continue to operate its own drug discount program through which it negotiates agreements directly with drug manufacturers to obtain rebates. As of July 1991, the HCFA still

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had not reached a decision regarding the waiver. However, the HCFA did contact the department in April 1991, indicating the waiver would be granted if the discounts Medi-Cal would receive from drug manufacturers under its drug discount program would be at least as great as those it would receive under the federal drug discount program. Moreover, the HCFA indicated the department is responsible for providing to the HCFA regional office in San Francisco requests for approval for proposed agreements between the department and drug manufacturers. An HCFA official indicated that, as of July 1991, Medi-Cal had submitted 16 agreements between the department and drug manufacturers for approval. However, according to the official, the HCFA had not yet announced a final decision concerning approval of these agreements.

Medi-Cal Uses Most of the Same Cost Controls as Other Major Pharmaceutical Purchasers

As we discussed in Chapter 1 of our report, our survey of major pharmaceutical purchasers revealed they use many utilization and price strategies to control the cost of pharmaceuticals. Medi-Cal uses most of the same utilization and price strategies as the major pharmaceutical purchasers in its attempt to stem the increase in its drug expenditures, but not all of the controls the major pharmaceutical purchasers use would be suitable for use by Medi-Cal because of Medi-Cal's system for delivering services. For example, at least one of the major pharmaceutical purchasers we surveyed buys drugs in bulk quantities. However, according to the department, Medi-Cal is not currently involved in buying drugs in bulk quantities. Instead, beneficiaries obtain prescription drugs at those California pharmacies that serve Medi-Cal beneficiaries. Any consideration of additional strategies Medi-Cal might use to lower its drug costs must take into account how Medi-Cal delivers health services to its beneficiaries since some strategies might require an overhaul of this delivery system.

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